Prepared Statement
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Senate Special Committee on Aging Hearing:
"Liability, Licensing and the Flu Vaccine Market: Making Decisions Today to Prevent a Crisis Tomorrow"

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I appreciate the opportunity to appear before you today. I recently chaired the Institute of Medicine's Committee on the Evaluation of Vaccine Purchase Finance in the United States. The full report, *Financing Vaccines in the 21st Century: Assuring Access and Availability,* was released in August 2003 and is published by the National Academies Press (2004). Although the report applied to childhood and adult vaccines in general, the findings and recommendations of the report have even greater force today than in late 2003, given the substantial shortage of flu vaccine the U.S. is currently experiencing. Although each shortage is unique, the current shortage follows a pattern of shortages for flu and other vaccines. While short-run solutions may be devised specifically for flu, the recent crisis represents an important wake-up call and presents an opportunity for consideration of longer-run and more comprehensive reforms.

The charge to the IOM committee was to: (1) examine current arrangements for purchasing and distributing vaccines; (2) identify strategies to ensure assess to vaccines and offer incentives for the development of new vaccines; and (3)

develop recommendation to guide public decision-making. The report was prepared by an 11-member committee, which included a broad range of perspectives, ranging from adult and pediatric medicine, vaccine and insurance industries, economics, and law. The committee commissioned a survey and eight independent studies covering such issues as vaccine industry and market structure and trends, vaccine pricing trends, insurance practices and coverage levels, and disparities in access to vaccines. The committee convened expert panels on the insurance and vaccine industries, and public health. More than 100 informational interviews and meetings were with stakeholders and others. The committee was hampered by lack of data, including data on vaccine manufacturing and R&D cost and on liability cost.

The national immunization system has achieved high levels of immunization for children, and progress has been made in adult immunization as well. In particular, the Vaccines for Children program instituted in 1994, has increased immunization rates for young children that are at historic highs.

Yet despite many successes, many problems remain. Structural and financial problems also plague the vaccine supply system, which are not unique to flu vaccine. For example, recent, unprecedented shortages in 8 of the 11 routine childhood vaccines caused serious delays in immunization. The committee was concerned about the degree of concentration of firms that produce vaccines for the

U.S. market. From 1966 to 1977, half of all commercial vaccine manufacturers stopped producing vaccines, and the exodus has continued. Today only 5 companies produce all vaccines recommended for routine use by children and adults, and only three of these are U.S.–based firms.[1] Eight critically important vaccine products have only one supplier. A long–term shut–down in capacity of any one of these companies could be devastating--experts suggest that it could take years to have a replacement vaccine licensed and available to the public in sufficient quantities. The current situation with flu vaccine, brought about by a dearth of suppliers, is a harbinger of shortages to come.

There are also problems in the delivery of vaccines to the public, particularly for childhood vaccines. Similarly, many adults do not have insurance coverage for recommended vaccines.

The fragmented system for financing immunizations burdens in physicians' offices--from identifying who is eligible for immunization coverage to creating separate storage areas for vaccines for different payers. Consequently, there is a risk that physicians refer patients to public health departments, which imposes extra time and inconvenience on patients and thus is a deterrent to being immunized. The committee was concerned that, as the costs of vaccines increase,

[1] More than five manufacturers are licensed to produce vaccines, but they produce non-routine vaccines such as for anthrax.

insurers may simply drop coverage for some or all vaccines or increase cost–sharing.

A strong relationship exists between the system for purchasing and providing vaccines to the public, on one hand, and stability and growth of the U.S. vaccine supply system on the other. The thrust of public policy for childhood vaccines has been to concentrate purchasing power in the federal government. The government uses its purchasing clout to negotiate substantial discounts and enforce price caps. Further growth of the government market share in vaccines is likely to create disincentives for private vaccine companies to develop new vaccines and to provide vaccines on a continuous and an as-needed basis. Lack of adequate financial incentives are responsible for the vulnerability to shortage we are experiencing today.

The committee considered several strategies ranging from incremental changes in the current system--for example, expansion of the Vaccines for Children program to include adults--to a system of complete governmental purchase of vaccines. Each alternative has its pluses and minuses; in the end, the committee's recommendations reflect a careful balancing of the major alternatives.

The approach ultimately selected was a unified approach to vaccine finance and is contained in the committee's three recommendations. The first proposes a substantial redesign of the system for purchasing and financing vaccines. This

recommendation states that the current system for purchasing and distributing vaccines should be replaced by a vaccine *mandate, subsidy* and *voucher* system.

The *mandate* would require that all public and private insurance plans cover immunizations that (1) yield benefits in excess of cost and (2) only for those groups for which benefits exceed cost, and (3) for immunizations with substantial spillovers or externalities—both health and financial. The mandate addresses several concerns, the major one being that many vaccines not only benefit the person being vaccinated, but others (even strangers) as well. The mandate would apply to all private insurers—both state regulated and self–insured employer plans, and to all public insurance plans.

The *subsidy* provision means that the federal government assumes responsibility for paying for vaccines that are being mandated, at least in part. Health plans will receive payment from the federal government for vaccine purchase costs and administration fees.

While the funded mandate would cover everyone who insured, the *voucher* provision would cover everyone who is uninsured. Under this plan, uninsured children and adults would receive immunizations from health care providers of their choice, and the government would reimburse providers for each vaccine plus an administration fee.

The committee proposed that a subsidy amount be determined for vaccines that are not yet available as a way to stimulate their development and licensure. The amount of the subsidy would be based on the total societal benefit of the vaccine – not 100% of the value, but some percentage of that amount that, at a minimum, reflects the health and financial benefits accruing to others than the person being vaccinated. Current vaccines require more modest incentives in order to maintain investment in current capacity, promote development of better versions of old vaccines, and stimulate additional firms to enter the field. Thus, the subsidy formulas for current and future vaccines might be different.

The expectation is that, on average, this approach will increase the prices of vaccines. While this may be a tough sell in today's fiscal environment, it is important to place this spending in context—the entire global market for all vaccines is about the same as for one of several blockbuster drugs.

The subsidy should be based on an objective benchmark—the actual savings to society resulting from the discovery and use of a vaccine. The subsidy should be set by an independent body, by a completely transparent process, and the methodology must be consistent across all vaccines. This is not however, a government fixed price, but rather a fixed dollar subsidy reflecting social benefit rather than either production or R&D cost.

The committee's second recommendation proposes changes to the composition and decision making process of the Advisory Committee on Immunization Practices (ACIP)—the entity that recommends vaccines for use by the public. The group would have responsibility for reviewing evidence on benefit versus cost for existing vaccines and those not yet developed, for identifying those populations for which the net benefit is the highest, and for setting the value of the fixed dollar subsidy.

The third recommendation calls for a public process of stakeholder deliberations to explore the full implications of the proposal and address technical design issues. There have been some public meetings since the release of the report but, to my knowledge, there has been no refinement of either the IOM committee's recommendations or the alternative policies examined in our report.

Events since the release of the report, in particular the experiences with flu vaccine both this year and in the previous year point to the need for change. Hopefully, as short-run solutions for the shortage of flu vaccine are examined, the current shortage will also be seen as an occasion for consideration of longer run reforms affecting flu as well as other vaccines.

Thank you.